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JUL 15 2009

510(K) Summary of Safety and Effectiveness
TRIMED STERILE PRODUCT

Submitted By:

TriMed, Inc.
25864 Tournament Road, Ste. A
Valencia, CA 91355
(800)633-7221

Registration #:

2031009

Prepared By/Contact Person:

Kelli Anderson
Phone: (661)312-7150
Fax: (661)254-8485

Proprietary Name:

TriMed Sterile Product

Classification:

Class II: Screw, Fixation, Bone
HWC - Section 888.3040
Class II: Plate, Fixation, Bone
HRS - Section 888.3030
Class II: Pin, Fixation, Smooth, Metallic
NDL - Section 888.3040
Class II: Nail, Fixation, Bone
JDS - Section 888.3030
Class II: Fastener, Fixation, Nondegradable, Soft Tissue
MBI - Section 888.3040
Class II: Pin, Fixation, Smooth
HTY - Section 888.3040

510(K)'s Being Modified:

K951302 - TriMed, Inc. (Formerly MEDPAC)
Small Fragment Plates & Screws
K951303 - TriMed, Inc. (Formerly MEDPAC)
SFC
K010545 - TriMed, Inc.
TBW

510(K)'s Being Modified (cont'd):

K040112 - TriMed, Inc.
Bearing & Volar Bearing Plate
K043263 - TriMed, Inc.
Osteotomy Plate
K060041 - TriMed, Inc.
Bone Plates
K081348 - TriMed, Inc.
Tenodesis Cross Screw, Interference Screw, Suture Bead

IV. Indications For Use:

The indications for use for each product cleared under 510(K) remains the same. The only difference in the product is that it will now be available sterile.

II. Device Description:

The products cleared in the 510(K)'s listed above will now be provided sterile by TriMed, Inc. No other changes have been made to the devices. Sterilization, packaging, aging and shipping validations have proven that the product can reach the end user while maintaining a sterility assurance level of 10^{-6}.

Kelli Anderson, M.S., RAC
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TriMed, Inc.
% OrthoCompliance
Ms. Kelli Anderson
28337 Maitland Lane
Saugus, California 91350

JUL 15 2009

Re: K091156
Trade/Device Name: Trimed Sterile Product
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, JDS, HWC, NDL, HTY, MBI
Dated: June 17, 2009
Received: June 19, 2009

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Barbara Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091156

Device Name: Small Fragment Plates and Screws

Used as an aid to the healing of volar rim fractures of the distal radius.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: SFC

Used as an aid to the treatment of certain types of fractures involving small fragments. Specifically:

- Cortical fragments large and strong enough to allow application of the device with fixation to an adjacent stable cortex of cortical bone.

- An intraarticular fragment large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone.

- A combination of the above

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: Tension Band Wire

Skeletal fractures that are amenable to the principle of tension band wiring. Typical sites of application may include but are not limited to fractures of the olecranon, patella, medial malleolus, lateral malleolus, distal ulna, distal humerus, and proximal humerus.

The decision to use a specific implant as well as the size and shape of the implant used must be based on sound medical judgement that takes into consideration factors such as the circumstances and configuration of the injury.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: TriMed Bearing Plate; TriMed Volar Bearing Plate

1. Fixation of fractures or non-unions of the distal radius
2. Osteotomies of the distal radius to correct malunion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: TriMed Osteotomy Plate

The TriMed Ulnar Osteotomy Plate is intended for use in osteotomy procedures of the ulna.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: TriMed Bone Plates

The TriMed Bone Plates are intended for use in the fixation of fractures to the Tibia, Fibula, Ulna, Radius and the Humerus.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: TriMed Tenodesis Cross Screw and Interference Screw

Indications For Use:

The TriMed Tenodesis Cross Screw and Interference Screw are intended to be used as an aid for fixation of soft tissue grafts to bone. Specific indications for use include:

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, Tendon Transfer in the hand and wrist.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruciton, Tendon Transfers in the foot and ankle.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K091156

Indications for Use

510(k) Number (if known): K091156

Device Name: TriMed Suture Bead

Indications For Use:

The TriMed Suture Bead is indicated as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. It may also be used as an adjunct to external and intramedullary fixation systems involving fixation plates and rods, with fracture braces and casting. The Suture Beads are also indicated in ligament and tendon repair and reconstruction associated with fractures and soft tissue reattachment.

The TriMed Suture Bead is not indicated for use within intra-articular sites.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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